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Re-evaluation Note REV2017-09

Special Review Decision: Atrazine

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Special Review Decision

Pursuant to subsection 17(2) of the *Pest Control Products Act*, the Pest Management Regulatory Agency (PMRA) initiated a special review of pest control products containing atrazine based on the decision taken by the European Commission in 2004 to prohibit all uses of atrazine. The PMRA evaluated the aspect of concern that prompted the special review in accordance with subsection 18(4) of the *Pest Control Products Act*. The proposed special review decision was published for consultation in the Re-evaluation Note REV2015-11, *Special Review of Atrazine: Proposed Decision for Consultation*, and it outlines the Agency's proposed decision and the reasons for it.

Comments received during the consultation process that were related to the aspect of concern (the potential for atrazine and its chlorinated transformation products to leach to groundwater) were taken into consideration in making the final special review decision and they did not result in changes to the proposed regulatory decision as described in REV2015-11. Appendix I summarizes the comments received related to the aspect of concern and provides the PMRA's response to these comments. The PMRA, under the authority of the *Pest Control Products Act*, is confirming the current registration of atrazine in Canada.

Regulatory Directive DIR2014-01, *Approach to Special Reviews*, presents the details of the PMRA's special review approach.

Other Information

Any person may file a notice of objection[1] regarding this decision on atrazine within 60 days from the date of publication of this special review decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of Health Canada's website, Request a Reconsideration of Decision, or contact the PMRA's Pest Management Information Service.

[1] As per subsection 35(1) of the *Pest Control Products Act*.

Appendix I

The PMRA received comments from stakeholders in response to Re-evaluation Note REV2015-11, *Special Review of Atrazine: Proposed Decision for Consultation*. The PMRA consolidated and summarized the comments related to this special review and provides responses below. Only comments related to the aspect of concern (the potential for atrazine and its chlorinated transformation products to leach to groundwater) and the special review process were addressed.

1.0 Scope of the Special Review of Atrazine

1.1 Comment on the aspect of concern for the special review

A special review conducted pursuant to subsection 17(2) should consider new information or emerging issues related to health and environmental risks of the subject pest control product, in particular data and studies that may not have been available to, or previously considered by PMRA. The special review of atrazine has not addressed other environment and human health issues including endocrine disruption, carcinogenicity and risk to aquatic species.

PMRA Response:
When a special review is initiated under subsection 17(2) (in other words, based on the prohibition of all uses of an active ingredient for health or environmental reasons in an Organisation for Economic Co-operation and Development (OECD) member country), the PMRA carries out an analysis of the OECD decision to identify the aspect(s) of concern related to the pest control products (in other words, the concern(s) that resulted in the prohibition of the active ingredient in the OECD country). For atrazine, the aspect of concern that prompted this special review was identified as the potential for atrazine and its chlorinated transformation products to leach to groundwater. As described in Regulatory Directive DIR2014-01, *Approach to Special Reviews*, the PMRA special review evaluation is targeted to address only the aspect(s) of concern related to the pest control product that prompted the special review.

1.2 Comment on individual products included in the special review

The proposed special review decision of atrazine does not examine individual end-use pest control products containing atrazine as required by the Act. Atrazine is found in some pest control products with other active ingredients such as dicamba, S-metolachor, mesotrione, bicyclopyrone, and Dimethenamid-P. The entire pest control product should be reviewed, including all of the active ingredients, their potential cumulative effects and synergies, as well as the impacts of co-formulants.

PMRA Response:
Under the *Pest Control Products Act*, a special review of all registered pest control products containing the active ingredient in question is required. Therefore, as part of this special review, the PMRA considered all registered pest control products (technical and end-use products) that contain atrazine, and the special review decision is applicable to all registered products. A list of the 13 products containing atrazine under special review was provided in Appendix I of REV2015-11. When assessing the potential leaching to groundwater, the PMRA considered the

environmental chemistry and fate information from laboratory, field and monitoring studies, and reviewed the risk-reduction measures included on all product labels related to the aspect of concern. While the laboratory studies in general are carried out with technical active ingredients, the field studies were conducted with end-use products containing the active ingredient under actual conditions of use in the field. Additionally, the monitoring data gives an indication of the fate of the active ingredient when used as a formulated product under actual use scenarios.

2.0 Science Evaluation

2.1 Comment on the information provided about the levels of atrazine in groundwater

Although numerous groundwater studies, many unpublished, are referenced in the REV2015-11, this original data was not provided during the consultation process and would not be available through the PMRA Reading Room until the final decision is made. The public cannot comment on a re-evaluation that hinges on concentrations of a pesticide and breakdown products in groundwater, without access to the groundwater data, as well as the detection limits applicable to each analysis.

PMRA Response:
REV2015-11 provides a summary of groundwater monitoring data for atrazine over a nine year period including over 14, 000 samples from Canada and the United States as well as the results of a targeted atrazine drinking water monitoring study from Ontario and Quebec (main use areas in Canada). The atrazine water monitoring information considered in REV2015-11 is a consolidation of many studies from both published and unpublished sources. Given the large volume of atrazine water monitoring information considered, the PMRA elected to provide only the maximum values obtained from all available water samples, as these maximum values are used in the drinking water risk assessment.

The *Pest Control Products Act* provides the public with the opportunity to inspect the scientific test data supporting a final decision to register a product, to amend a registration or to continue a registration after a re-evaluation or a special review. Since the unpublished test data are provided to the PMRA in confidence and may be protected from public disclosure under the *Access to Information Act*, the data cannot be distributed publically. The data may be inspected in the PMRA Reading Room following the final decision but cannot be copied or removed from the premises.

2.2 Comment on the levels of atrazine in groundwater

Atrazine was detected in 11% of groundwater samples in Canada (119 out of 1067), with a maximum concentration of 2.32 µg/L. The maximum concentration reported by the PMRA in the special review is well in excess of the 0.1 µg/L concentration used by the European Union as a reason to ban atrazine. Clearly the European limit of 0.1 µg/L is being exceeded in Canadian groundwater, but it is unclear what level of atrazine in groundwater is claimed not to have been exceeded.

PMRA Response:
The European Union relies on a level of 0.1 µg/L as the maximum acceptable concentration for any individual pesticide in groundwater. The 0.1 µg/L threshold is a legislated, rather than risk-based, value that applies to all pesticides regardless of their toxicity to humans. Conversely, the PMRA follows a risk-based scientific approach in determining the risk to human health from pesticides in drinking water. This approach takes into consideration both the estimated level of the pesticide in drinking water sources (exposure) and the toxicity of the pesticide (hazard).

The PMRA has not established a level of atrazine that cannot be exceeded in groundwater. Rather, the PMRA has conducted a drinking water risk assessment taking into consideration the toxicity of atrazine and its chlorinated transformation products and the highest concentrations expected in groundwater. Based on this scientific approach, the PMRA has concluded that there are no acute or chronic risks of concern from atrazine in groundwater at the maximum detected concentration in Canadian groundwater monitoring data of 2.32 µg/L. Furthermore, aggregate exposure to food and drinking water is not of concern as described in REV2015-11.

2.3 Comment on the levels of atrazine in the targeted drinking water monitoring study

For the targeted drinking water monitoring study conducted by the technical registrant, REV2015-11 indicates that total chlorotriazine levels did not exceed the Canadian drinking water guideline of 5 µg/L, but did not specify the actual levels for atrazine detections below 5µg/l and therefore was not representative of actual groundwater atrazine levels and potential risk.

PMRA Response:
The drinking water monitoring study measured atrazine and its associated metabolites in 10 municipal water supplies located in corn-growing regions of Ontario and Quebec. Levels of atrazine from groundwater sources ranged from below the limit of detection (<0.02 µg/L) to 0.047 µg/L in raw and treated water. The maximum total chlorotriazine levels ranged from below the limit of detection (<0.02 µg/L) to 0.46 µg/L in raw and treated water sourced by groundwater.

2.4 Comment on the Canadian Drinking Water Guideline

The Canadian Drinking Water Guideline set by Health Canada for atrazine is 5 µg/L which is 50 times higher than the European limit of 0.1 µg/L. The US drinking water standard is 3 µg/L which is 40% lower than Canada. The PMRA modelled potential residues of atrazine in groundwater to estimate contamination of drinking water sources. The highest estimated environmental concentration in groundwater was modelled at 164 µg/L which is over 30 times the Canadian drinking water guideline. The PMRA used a comparator in the special review called the Drinking Water Level of Comparison of 1300.5 µg/L for acute effects and 41.9 µg/L for chronic effects rather than the Canadian Drinking Water Guideline. This is less precautious and less protective of human health and the environment, which runs counter to the precautionary basis of the Act. It is unclear at what levels atrazine was actually measured in North America, and whether the levels were less than the Canadian Drinking Water Guideline (5 µg/L), or the PMRA Drinking Water Level of Comparison of 41.9 µg/L.

PMRA Response:
The PMRA used a drinking water level of comparison (DWLOC) as a point of comparison against estimated concentrations of atrazine in groundwater. The DWLOC values are theoretical upper limits of a pesticide's concentration in drinking water that would not be of concern in light of the total exposure to a pesticide in food and drinking water. The PMRA drinking water risk assessment takes into account the actual expected exposure to atrazine from food only and derives a maximum acceptable concentration in drinking water that would not be of concern when exposure through both food and drinking water are combined.

Exposure to atrazine from food alone represents <1% of the acceptable level (acute and chronic basis). Taking into account the total acceptable exposure to atrazine and the exposure from food alone, levels of atrazine up to the theoretical levels of 1300.5 µg/L and 41.9 µg/L would not be of concern for the most sensitive population on an acute and chronic basis, respectively.

Groundwater monitoring data for atrazine is extensive. REV2015-11 provides a summary of groundwater monitoring data for atrazine over a nine year period including over 14, 000 samples from Canada and the United States as well as the results of a targeted atrazine drinking water monitoring study from Ontario and Quebec (high atrazine use areas). The maximum detected concentration of atrazine in Canadian groundwater monitoring data is 2.32 µg/L and 18.8 µg/L in the United States. The drinking water monitoring study from Ontario and Quebec found levels of atrazine from groundwater sources ranging from below the limit of detection (<0.02 µg/L) to 0.047 µg/L. Both the levels detected in Canadian monitoring data, and the drinking water monitoring study, are below both the PMRA DWLOCs as well as the Canadian Drinking Water Guideline of 5 µg/L.

The modeled level of 164 µg/L in groundwater, described in REV2015-11, is a maximum concentration that is expected to be a conservative estimate. For chronic exposure, while the modeled value numerically exceeds the PMRA chronic drinking water level of comparison (41.9 µg/L) exposure is not expected to be of concern taking into account the extensive groundwater monitoring information that is available for atrazine where the maximum concentration was 2.32 µg/L in Canada.

See also PMRA responses to 2.2 and 2.3.

2.5 Comment related to levels of atrazine in high usage areas

Atrazine is the most often detected compound in US groundwater. We can expect atrazine detection to be geographically variable and correlate with corn production areas. Additional studies were provided with comments indicating levels of atrazine in various regions.

PMRA Response:
The PMRA agrees that atrazine detections would be geographically variable. It is for this reason that the targeted drinking water monitoring study described in REV2015-11 focussed on the corn-growing regions of Ontario and Quebec, which represent the major atrazine use area in Canada. Levels of atrazine from groundwater sources in Ontario and Quebec ranged from below the limit of detection (<0.02 µg/L) to 0.047 µg/L in raw and treated drinking water.

The PMRA considered the additional studies provided with the comments and determined that the reported levels of atrazine in groundwater (below 2.32 µg/L) fall within the range considered in REV2015-11.

2.6 Comment related to cumulative effects

The current system of assessing pesticides on an individual basis without a cumulative total acceptable pesticide concentration as in Europe represents a serious omission with potential for long term consequences.

PMRA Response:
The PMRA considers cumulative health effects of pest control products when a common mechanism of toxicity is identified with other pest control products. Health Canada's Science Policy Note SPN2001-01, *Guidance for Identifying Pesticides that have a Common Mechanism of Toxicity for Human Health Risk Assessment*, describes the steps for identifying mechanisms of toxicity of pesticides that cause a common toxic effect, the types of data needed and their sources, how these data are to be used in reaching conclusions regarding commonality of mechanisms of toxicity, and the criteria Health Canada applies for categorizing pesticides for the purpose of cumulative assessment. The PMRA did consider triazine cumulative effects in REV2015-11 and concluded that a common mechanism of toxicity has not been identified for atrazine and any other pest control products not in the triazine group, nor is atrazine considered to produce a metabolite common to other active ingredients not part of the triazine group of products. Cumulative exposure to triazine residues through drinking water exposure was not of concern to human health.

It was further noted that an updated cumulative assessment for triazines is ongoing as part of the United States Environmental Protection Agency Registration Review for atrazine (USEPA Registration Review Docket ID: EPA-HQ-OPP-2013-0266). The PRMA will continue to monitor and work with the United States counter parts on cumulative effects associated with atrazine.

2.7 Comment related to the Canadian Water Quality Guideline

The Canadian Environmental Quality Guidelines environmental aquatic benchmark of concern for atrazine is 1.8 parts per billion. The Minister should reduce the maximum allowable concentration in drinking water and to establish an enforceable maximum allowable concentration no higher than 1.8 parts per billion of atrazine in groundwater and surface waters to better protect human health and aquatic life.

PMRA Response:
The Canadian water quality guideline for atrazine for the protection of freshwater life (1.8 ppb) pertains to surface water. The aspect of concern for the special review was related to the potential leaching of atrazine and its chlorinated metabolites to groundwater. Potential risk to aquatic species is not considered in the special review.

For the groundwater assessment, the PMRA has followed a risk-based scientific approach in determining the risk to human health from pesticides in drinking water sourced from groundwater. This approach takes into consideration both the estimated level in drinking water sources (exposure) and the toxicity of the pesticide. Based on the drinking water risk assessment for atrazine, the PMRA concludes that there are no acute or chronic risks of concern from groundwater at the current levels.

See also PMRA responses to 2.2, 2.3 and 2.4.

2.8 Comment related to timing for water sampling

Did groundwater testing include testing during spring run off or other seasons when concentrations would be higher?

PMRA Response:
As part of the special review for atrazine, a search for groundwater monitoring data for atrazine in Canada was conducted. Representatives of the Canadian Federal Provincial and Territorial Committee on Pest Management and Pesticides Committee as well as the Federal Provincial and Territorial Committee on Drinking Water were contacted, along with researchers at Environment Canada and the provinces, requesting groundwater monitoring data for atrazine. The request also encompassed data from water distribution systems sourced by groundwater. Since the data came from many sources, sample collection times varied. For example, in one study samples were collected in May and June, but in another study sampling occurred in late fall and early winter to coincide with the fall groundwater recharge period. All the samples, regardless of the source or the sample collection time, were considered as a whole.

In addition, the technical registrant submitted a targeted drinking water monitoring study in 2006, from atrazine major use areas (Ontario and Quebec) to monitor levels of atrazine and its chlorinated transformation products in Canadian raw and finished (untreated and treated) drinking water from sites representing the most vulnerable watersheds. These samples were collected between April and September of 2005.

2.9 Comment related to the persistence of atrazine in groundwater

The PMRA assessment of the environmental fate of atrazine appears not to have included the serious long term studies on the persistence and bioaccessibility of atrazine and its metabolites. Research has demonstrated persistence many times longer than the laboratory studies quoted by the PMRA Atrazine Review. In some cases, atrazine's demonstrated persistence in groundwater is in excess of 20 years. Additional references to studies were provided in support of the comment.

PMRA Response:
As described in REV2015-11, the PMRA has concluded that atrazine is persistent in aquatic systems. The PMRA drinking water risk assessment has considered groundwater monitoring data for atrazine over a nine year period including over 14,000 samples from Canada and the United States, as well as the results of a targeted atrazine drinking water monitoring study from Ontario and Quebec. This multi-year dataset would capture any potential persistence in groundwater.

2.10 Comments on atrazine risk conclusions

The Special Review Decision for Atrazine states that the: "Evaluation of available relevant scientific information related to the aspect of concern, indicates that atrazine and its chlorinated transformation products do not pose unacceptable risks to human health and the environment, with respect to drinking water, taking into account the current conditions of use." The statement clearly implies that atrazine and its metabolites may pose acceptable risks. What are the potential risks that the decision is accepting? How did the PMRA determine what level of risk is acceptable and what experiments were conducted that show that the use of atrazine does not exceed the acceptable risks? Do any scientific experts disagree with the PMRA's conclusion? What evidence or reasons do they cite and how does the PMRA respond?

PMRA Response:
As part of the special review, the PMRA has conducted a risk-based scientific assessment to determine the risk to human health from pesticides in drinking water sourced from groundwater.

The purpose of conducting a human health risk assessment is to define the nature of the risk and to provide a measure of the likelihood and the magnitude of the risk associated with a defined exposure. The determination of whether the exposure is acceptable is made by comparing the estimated human exposure to the toxicology reference dose. Exposures that fall below the reference dose are considered to provide sufficient margins of safety and are unlikely to be associated with risks of concern to health.

As described in REV2015-11, the PMRA conducted a drinking water risk assessment to determine whether exposure to atrazine and its chlorinated transformation products through Canadian groundwater presents a potential risk of concern to Canadians. The estimated exposure to atrazine and its chlorinated transformation products in groundwater was below the drinking water level of comparison (both acute and chronic). On this basis, exposure to atrazine at the expected level in drinking water is not of concern.

Before making a final decision, the PMRA solicits public comments, as was done in REV2015-11. The PMRA received comments from non-governmental organisations, grower organisations, academia and the general public. This document contains the PMRA response to all the comments received related to the aspect of concern for the special review of atrazine.

2.11 Comment related to water treatment

Conventional drinking water treatment is not effective at removing atrazine from water. The Canadian Water and Wastewater Association has expressed concern regarding the cost and difficulty of removing pesticides such as atrazine from contaminated water. Its members would prefer to see effective prevention so that source water does not become contaminated. Rural residents, whose water is more likely to be affected by atrazine used on local farms and whose drinking water may by insufficiently treated, may be at higher risk than urban Canadians.

PMRA Response:
The ability of water treatment systems to remove or decrease levels of atrazine in drinking water will vary by treatment facility and purification methodology. The PMRA drinking water assessment has taken into consideration measured levels of atrazine in both raw groundwater and treated groundwater, including in high atrazine usage areas of Ontario and Quebec. The risk assessment is considered protective of treated and untreated groundwater-sourced drinking water in both urban and rural settings.

2.12 Comment related to the *Pest Control Products Act* factor

The special review has not considered the additional safety factor required by the *Pest Control Products Act*.

PMRA Response:
As described in REV2015-11, for assessing risks from potential residues in drinking water, the *Pest Control Products Act* requires the application of an additional 10-fold factor to threshold effects to take into account completeness of the data with respect to the exposure of, and toxicity to, infants and children, and potential prenatal and postnatal toxicity. A different factor may be determined to be appropriate on the basis of reliable scientific data. The atrazine database contains the full complement of required studies including developmental studies in rats and rabbits, and a reproductive study in rats. There was no evidence of increased quantitative or qualitative sensitivity to rat or rabbit offspring following in utero and/or postnatal exposure to atrazine. Reference doses for atrazine were based on no observed adverse effect levels (NOAELs) for the most relevant endpoints, namely attenuation of the luteinizing hormone surge, estrous cycle alterations and developmental effects. These reference doses incorporate uncertainty factors to account for extrapolation between rats and humans and for variability within human populations, as well as an additional safety factor to provide an extra level of protection for the potential neuroendocrine modulating effects of atrazine. Therefore, on this basis, the *Pest Control Products Act* factor was reduced from 10-fold to 1-fold.

2.13 Comment related to risk from use of atrazine

The PMRA's proposed special review decision for atrazine, does not consider that those taking the risk (people who drink water) are not the same people who obtain the reward (those who sell and use atrazine) and the people potentially harmed are not in a position to decide to take the risk, as they may not know whether their water contains atrazine, nor have access to alternative water supplies.

PMRA Response:
The PMRA drinking water assessment has taken into consideration measured levels of atrazine in both urban and rural settings. The risk assessment is protective of all Canadians regardless of age and location. That is, exposure through drinking water was not of concern to human health for any population subgroup.

2.14 Comments related to the precautionary principle

The PMRA is urged to apply the precautionary principle with respect to atrazine and take regulatory action to prohibit or limit the use in Canada. Are the precautionary principles applied by the PMRA different from those in the European Union and Switzerland where atrazine has been banned? Would the government's renewed commitment to strengthen research and evidence-based policies not require a more rigorous and thorough review of health and environmental risks?

PMRA Response:
The PMRA has conducted a science-based drinking water risk assessment taking into consideration the toxicity of atrazine and its chlorinated transformation products and the highest concentrations expected in groundwater. Based on this scientific approach, the PMRA has concluded that there are no acute or chronic risks of concern from atrazine in groundwater at the maximum detected concentration in Canadian groundwater.

3.0 General Comments

3.1 Comment related to consultation with independent scientists

The PMRA should consult independent scientists to determine the safety of products it approves.

PMRA Response:
The special review has considered all available information pertaining to atrazine in groundwater including results and conclusions from independent researchers in Canada and as well as studies provided by the atrazine registrant. Studies submitted by registrants are conducted in accordance with international test guidelines. Use of registrant supplied studies is standard practice in regulatory Agencies around the world. The raw data generated in the submitted studies are independently evaluated by PMRA scientists. For more information on the types of studies required for conducting health, environmental and value assessments for pesticides, as well as on the review process, please refer to Health Canada's PMRA website: http://www.hc-sc.gc.ca/cps-spc/pest/index-eng.php.

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